

JS 44 (Rev. 12/07, NJ 5/08)

**CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**

United States, et al., ex rel. Dele Obaitan

(b) County of Residence of First Listed Plaintiff \_\_\_\_\_

(c) Attorney's (Firm Name, Address, Telephone Number and Email Address)

Robert A. Magnanini, Esq.  
Stone & Magnanini LLP  
150 JFK Parkway, 4th floor, Short Hills, NJ 07078  
(973) 218-1111 rmagnanini@stonemagnalaw.com

**DEFENDANTS**

Pricara, a unit of Ortho-McNeil, a division of Ortho-McNeil  
Janssen Pharmaceuticals, Inc. +

County of Residence of First Listed Defendant Somerset

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE  
LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff  
☐ 2 U.S. Government Defendant  
☐ 3 Federal Question (U.S. Government Not a Party)  
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                        | DEF                        |   | PTF                        | DEF                        |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition		

**V. ORIGIN**

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding  
☐ 2 Removed from State Court  
☐ 3 Remanded from Appellate Court  
☐ 4 Reinstated or Reopened  
☐ 5 Transferred from another district (specify)  
☐ 6 Multidistrict Litigation  
☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
31 U.S.C. 3729 et seq.

Brief description of cause:  
 Action for damages under the False Claims Act

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S)**

(See instructions):

JUDGE \_\_\_\_\_

DOCKET NUMBER \_\_\_\_\_

Explanation:

DATE

SIGNATURE OF ATTORNEY OF RECORD

12/21/10

**UNITED STATES DISTRICT COURT  
FOR THE  
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA,  
STATE OF CALIFORNIA,  
STATE OF DELAWARE,  
STATE OF FLORIDA,  
STATE OF GEORGIA,  
STATE OF HAWAII,  
STATE OF ILLINOIS,  
STATE OF INDIANA,  
STATE OF LOUISIANA,  
COMMONWEALTH OF  
MASSACHUSETTS,  
STATE OF MICHIGAN,  
STATE OF NEVADA,  
STATE OF NEW HAMPSHIRE,  
STATE OF NEW JERSEY,  
STATE OF NEW MEXICO,  
STATE OF NEW YORK,  
STATE OF OKLAHOMA,  
STATE OF RHODE ISLAND,  
STATE OF TENNESSEE,  
STATE OF TEXAS,  
COMMONWEALTH OF VIRGINIA,  
STATE OF WISCONSIN,  
and DISTRICT OF COLUMBIA,

*ex rel.* [UNDER SEAL],

Plaintiffs,

v.

[UNDER SEAL],

Defendant.

**COMPLAINT  
FILED UNDER SEAL  
PURSUANT TO  
31 U.S.C. § 3730(b)(2)**

**UNITED STATES DISTRICT COURT  
FOR THE  
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA, )  
STATE OF CALIFORNIA, )  
STATE OF DELAWARE, )  
STATE OF FLORIDA, )  
STATE OF GEORGIA, )  
STATE OF HAWAII, )  
STATE OF ILLINOIS, )  
STATE OF INDIANA, )  
STATE OF LOUISIANA, )  
COMMONWEALTH OF )  
MASSACHUSETTS, )  
STATE OF MICHIGAN, )  
STATE OF NEVADA, )  
STATE OF NEW HAMPSHIRE, )  
STATE OF NEW JERSEY, )  
STATE OF NEW MEXICO, )  
STATE OF NEW YORK, )  
STATE OF OKLAHOMA, )  
STATE OF RHODE ISLAND, )  
STATE OF TENNESSEE, )  
STATE OF TEXAS, )  
COMMONWEALTH OF VIRGINIA, )  
STATE OF WISCONSIN, )  
and DISTRICT OF COLUMBIA, )

*ex rel.* DELE OBAITAN, )

Plaintiffs, )

v. )

PRICARA, a unit of )  
ORTHO-MCNEIL, a division of )  
ORTHO-MCNEIL JANSSEN )  
PHARMACEUTICALS, INC. )

Defendants. )

**COMPLAINT  
FILED UNDER SEAL  
PURSUANT TO  
31 U.S.C. § 3730(b)(2)**

On behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Rhode Island, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, and the District of Columbia (collectively the “States”), Plaintiff and Relator Dele Obaitan (“Mr. Obaitan” or “Relator”) files this *qui tam* complaint against Defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMJP”), Ortho-McNeil, and PriCara (collectively, “Defendants”) and alleges as follows:

## **I. INTRODUCTION**

### **A. Federal Law Claims**

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America in connection with Defendant’s defrauding the United States Government through the off-label marketing and promotion of, and the provision of kickbacks and illegal incentives in connection with, certain pharmaceutical products in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the “FCA”).

2. Pursuant to the FCA, Relator seeks to recover, on behalf of the United States of America, damages and civil penalties arising from false or fraudulent claims that Defendant submitted or caused to be submitted to Federal Government funded health insurance programs for Defendant’s medical device procedures, including payments made by Medicare, Medicaid, the Federal Employees Health Benefits Program (“FEHBP”), the managed care component of

the United States Department of Defense Military Health System (“TRICARE”), and the Civilian Health and Medical Program of the Department of Veterans Affairs (“CHAMPVA”).

**B. State Law Claims**

3. This is also an action to recover double and treble damages and civil penalties on behalf of the named States arising from the conduct of Defendant who: (a) made, used or presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the States; and/or (b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the States, all in violation of each State’s respective false claims act or similar statute. The false or fraudulent claims, statements and records at issue involve payments made by health insurance programs funded by these State governments, including Medicaid.

4. The statutes of the States under which Relator brings these related actions are the:

- a. California False Claims Act, Cal. Govt. Code § 12651 *et seq.*;
- b. Delaware False Claims and Reporting Act, Del Code Ann. tit. 6, § 1201 *et seq.*;
- c. Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*;
- d. Georgia False Medicaid Claims Act, Ga. Code. Ann. § 49-4-168.1 *et seq.*;
- e. Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*;
- f. Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*;
- g. Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*;

- h. Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*;
- i. Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, § 5A *et seq.*;
- j. Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*;
- k. Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*;
- l. New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b;
- m. New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*;
- n. New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*, and New Mexico Fraud Against Tax Payers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*;
- o. New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*;
- p. Oklahoma Medicaid False Claims Act, 63 Okla. St. Ann. § 5053 *et seq.*;
- q. The State False Claims Act (Rhode Island), R.I. Gen. Laws § 9-1.1-1 *et seq.*;
- r. Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*;
- s. Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.002;
- t. Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*;
- u. Wisconsin False Claims for Medical Assistance Law, Wisc. Stat. § 20.931; and the
- v. District of Columbia False Claims Act, D.C. Code Ann. § 2-308.03 *et seq.*

## **II. SUMMARY OF THE ALLEGATIONS**

5. Defendants have defrauded the Government by marketing and promoting certain of their brand name pharmaceutical products for uses unapproved by the U.S. Food and

Drug Administration (“FDA”), and by providing kickbacks and illegal incentives to physicians to promote the off-label use of these drugs.

6. Relator Dele Obaitan, a licensed pharmacist who worked as a sales rep for Pricara, Ortho-McNeil, Janssen, and related and predecessor entities, personally learned of and witnessed Defendants’ marketing practices. Mr. Obaitan was not only trained to engage in improper marketing, he was directed to do so by management.

7. Defendants unlawfully marketed Pricara’s medicine Nucynta, approved in 2009 by the FDA for treatment acute pain, for chronic pain. Pricara’s marketing was obviously improper to Mr. Obaitan, in part because Pricara management directed the sales force to target pain-management practices, whose practitioners would rarely, if ever, have occasion to prescribe acute-pain medicine.

8. Defendants improperly and unlawfully marketed Topamax, a medicine approved for the treatment of epilepsy and for the prevention of migraine headaches, as a weight-loss drug. Specifically, Pricara marketed Topamax to psychiatrists and other mental-health providers as a way for patients who were taking antipsychotic drugs to avoid or counteract weight gain, a common side-effect of such drugs.

9. Defendants also seek to improperly induce doctors and other health-care providers to prescribe these drugs by engaging high-prescribing doctors as paid speakers, and conversely, denying doctors who did not prescribe sufficient quantities of their drugs the opportunity for such speaker engagements. In reality, these speaker programs were not for the purpose of medical education, but rather, were blatant financial incentives amounted to kickbacks.

10. In sum, and as described more fully herein, Defendants violated the federal and state False Claims Acts by engaging in fraudulent, deceptive, and illegal marketing, sales and business practices which resulted in the federal and state governments paying for medications they should not have paid for. The resulting damages to the federal and state governments – and the taxpayers – are potentially in the tens of millions of dollars.

### **III. JURISDICTION AND VENUE**

11. Pursuant to 28 U.S.C. § 1331, this Court has jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particularly the False Claims Act, 31 U.S.C. § 3729 *et seq.*

12. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the States on the ground that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

13. In addition, the FCA specifically confers jurisdiction upon United States District Courts under 31 U.S.C. § 3732. This court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant is headquartered and transacts business in the District of New Jersey.

14. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because certain of the acts complained of herein occurred in the District of New Jersey.

15. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and Defendant has sufficient minimum contacts with the United States of America.



16. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint has been filed *in camera* and will remain under seal for a period of at least 60 days and shall not be served on the Defendant until the Court so orders.

17. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator must provide the Government with a copy of the Complaint and/or a written disclosure of substantially all material evidence and material information in his possession contemporaneous with the filing of the Complaint. Relator has complied with this provision by serving copies of this Complaint upon the Honorable Paul J. Fishman, United States Attorney for the District of New Jersey, and upon the Honorable Eric H. Holder, Attorney General of the United States.

18. Relator is not aware that the allegations in this Complaint have been publicly disclosed. Further, to the extent Relator is aware of any public disclosures, this Complaint is not based on such public disclosures. In any event, this Court has jurisdiction under 31 U.S.C. § 3730(e)(4) because the Relator is an “original source” because he has provided his information voluntarily to the Government before filing this Complaint, and has knowledge which is both direct and independent of any public disclosures to the extent they may exist.

#### **IV. THE PARTIES**

19. Relator Bamidele (“Dele”) Obaitan is a resident of Land O’ Lakes, Florida. He has a B.S. in Pharmacy (*cum laude*) from Temple University, and an M.B.A. from Temple’s Fox School of Business and Management.

20. Mr. Obaitan was a licensed pharmacist of the Commonwealth of Pennsylvania (license currently inactive), is a licensed pharmacist of the State of Florida, and recently passed his examination for a Florida consultant pharmacist license. From 1992 through 2000, he

worked as a staff pharmacist in Philadelphia, first at Neumann Medical Center, and then at Pennsylvania Hospital (affiliated with the University of Pennsylvania).

21. Mr. Obaitan has extensive experience as a pharmaceutical sales representative. In 2002, he joined Johnson & Johnson's Janssen subsidiary as a sales representative. In 2005 he transferred to the Ortho-McNeil subsidiary, and in September 2008 he transferred to Pricara.

22. Mr. Obaitan had a successful career at Janssen, Ortho-McNeil, and Pricara. He had an exemplary employment record, and was frequently paid bonuses and other incentive compensation for meeting sales goals. During his employment, he was promoted to Professional Sales Representative and to Senior Professional Sales Representative. He served as a Regional, Home Office and Field Trainer.

23. Among other corporate recognitions, Mr. Obaitan received the Eagle Award for leadership, Johnson & Johnson Global Standards Leadership awards, District Rep of the Cycle (on several occasions), District Rep of the Year, and a Regional Detail award. The company recognized Mr. Obaitan for his accomplishments and leadership skills by placing him in the managerial development program, and appointing him on two occasions as interim District Manager. However, on or about September 29, 2009, he went on medical disability, and on or about March 2010, Mr. Obaitan left Pricara.

24. From his employment at Pricara, Mr. Obaitan gained direct and personal knowledge of the facts alleged herein.

25. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. is a pharmaceutical company formed by the 1993 merger of Ortho Pharmaceutical Corporation and McNeil Pharmaceutical. OMJP is headquartered at 1000 U.S. Route 202 South, Raritan, NJ.

26. OMJP is a wholly-owned subsidiary of Johnson & Johnson (“J&J”). J&J’s U.S. pharmaceutical sales for fiscal year 2009 exceeded \$13 billion.

27. Ortho-McNeil is a division of OMJP which markets products to hospitals and other healthcare institutions.

28. PriCara is a unit of Ortho-McNeil which markets products to primary care physicians (“PCPs”) to treat pain, acid reflux and infectious diseases, including the oral analgesics Nucynta and Ultram ER.

## **V. GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT**

### **A. The False Claims Act.**

29. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government’s ability to recover losses sustained as a result of fraud against the United States.

30. The FCA imposes liability upon any person who “knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval”; or “knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim”; or “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. §§ 3729(a)(1)(A), (B), (G). Any person found to have violated these provisions is liable for a civil penalty of up to \$10,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

31. Significantly, the FCA imposes liability where the conduct is merely “in

reckless disregard of the truth or falsity of the information” and further clarifies that “no proof of specific intent to defraud” is required. 31 U.S.C. § 3729(b)(1).

32. The FCA also broadly defines a “claim” as one that includes “any request or demand, whether under a contract or otherwise, for money or property . . . that . . . is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.” 31 U.S.C. § 3729(b)(2)(A).

33. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene in the action. 31 U.S.C. § 3730(b).

34. In this action, the Defendants failed to comply with anti-kickback statutes and regulations material to its products’ qualifications for federal and state reimbursement.

**B. Federal Government-Funded Health Assistance Programs.**

**1. Medicare.**

**a. Generally.**

35. Medicare is a federal government-funded medical assistance program, primarily benefiting the elderly, that was created in 1965 when Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* Medicare is administered by the federal Centers

for Medicare and Medicaid Services (“CMS”), known prior to 2001 as the Health Care Financing Administration, which is a division of the U.S. Department of Health and Human Services (“HHS”). Since 2006, Medicare Part D has provided optional prescription-drug coverage to persons eligible for Medicare coverage.

**b. The Stark Law’s Prohibition Against Certain Financial Relationships.**

36. Under the Stark Law section of Medicare, if a physician has a direct or indirect financial relationship with an entity (*e.g.*, a drug manufacturer), then “the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter.” 42 U.S.C. § 1395nn(a) and 42 C.F.R. § 411.353. The implementing regulations specifically define “designated health services” (“DHS”) to include “[o]utpatient prescription drugs.” 42 C.F.R. § 411.351 (“Definitions”). Thus, if a physician has a direct or indirect financial relationship with a drug manufacturer, the physician may not prescribe that manufacturer’s drugs to patients covered by federally-funded healthcare programs.

37. The Stark Law incorporates many of the same concepts and terminology set forth in the Anti-Kickback Statute, such as prohibiting compensation to a physician that takes into account the “volume or value” of referrals to the entity.

38. The Stark Law also specifically incorporates portions of the Anti-Kickback Statute (*e.g.*, 42 U.S.C. § 1320a-7a concerning civil monetary penalties) and also imposes its own civil penalties of \$15,000 for each false claim caused to be presented which is found to be the product of an improper financial arrangement. 42 U.S.C. § 1395nn(g)(3). In addition, the law heavily targets the entities (*e.g.*, drug manufacturers) dealing with physicians and imposes a \$100,000 civil penalty upon the entity “for each such arrangement or scheme.” 42 U.S.C. §

1395nn(g)(4).

39. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that pharmaceutical drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Defendant's wrongdoing.

**2. Medicaid.**

**a. Generally.**

40. The Medicaid program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the medically needy aged, the blind, the disabled, and needy families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both federal and state monies, (collectively referred to as "Medicaid Funds"), with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). At the federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a state Medicaid agency to administer the program.

41. Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the HHS. Among other forms of medical assistance, the states are permitted to provide medical assistance from the Medicaid Funds to eligible persons for inpatient and outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12).

42. Federal law prescribes that drug manufacturers must pay rebates to the states to insure that the Medicaid Rebate Program is paying the lowest price the manufacturer sells a

covered outpatient drug to any purchaser in the United States, inclusive of cash discounts, free goods, kickbacks, volume discounts and rebates. The best price provision is intended to ensure that the government is being provided the lowest price on drugs.

**3. General Provisions Applicable to Both Medicare and Medicaid.**

**a. “Medically Accepted Indication” Precondition for Reimbursement of Prescription Drugs.**

43. The Medicaid program reimburses only for “covered outpatient drugs” for which a rebate is paid by the drug’s manufacturer. 42 U.S.C. § 1396b(i)(10). The term “covered outpatient drug” requires use for a “medically accepted indication.” 42 U.S.C. § 1396r-8(k)(3).

44. A “medically accepted indication” includes only those indications approved by the FDA, and those “off-label” uses that are “supported by one or more citations included or approved for inclusion in any of the compendia” listed in the statute. 42 U.S.C. § 1396r-8(k)(6); *see also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying the compendia to be consulted).

45. Each state Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a “medically accepted indication.” 42 U.S.C. § 1396r-8(d)(1)(B).

46. Medicare Part D defines a covered drug as one “that may be dispensed only upon a prescription,” and expressly incorporates by cross-reference the Medicaid provisions excluding coverage for drugs prescribed “off-label” as described in the preceding paragraphs. 42 U.S.C. § 1395w-102.

**b. Prohibitions Against Claims for Services that are Not Medically Necessary or are Otherwise False or Fraudulent.**

47. Federal law prohibits a person from knowingly presenting or causing to be

presented to Medicare or Medicaid a claim for a medical or other item or service that the person knows or should know was “not provided as claimed,” a claim for such items or services that is “false or fraudulent,” or a claim that is “for a pattern of medical or other items or services that [the] person knows or should know are not medically necessary.” 42 U.S.C. §§ 1320a-7a(a)(1)(A), (B) & (E). A violation of this section is subject to a civil monetary penalty of \$10,000 for each item or service, plus damages measured as three times the amount of each claim submitted, and exclusion from further participation in the programs.

**c. The Anti-Kickback Statute Ensures Integrity of Underlying Conduct.**

48. The Anti-Kickback Statute prohibits kickbacks by providing a civil monetary penalty of \$50,000 for each act by an individual or entity that violates 42 U.S.C. § 1320a-7a(a)(7), which defines “[i]mproperly filed claims” as “[a]ny person (including an organization, agency, or other entity . . . ) that . . . commits an act described in paragraph (1) or (2) of section” 1320a-7b(b) of this title. The statute defines “illegal remuneration” (*i.e.*, kickbacks) as:

(1) Whoever knowingly and willfully *solicits or receives* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –

\* \* \*

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

\* \* \*

(2) Whoever knowingly and willfully *offers or pays* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

\* \* \*

(B) to purchase, lease, order, or arrange for or recommend



purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

42 U.S.C. § 1320a-7b(b) (emphasis added). The offense is also a felony punishable by fines of up to \$25,000 and imprisonment for up to five years. 42 U.S.C. § 1320a-7b(b).

49. In accordance with the Anti-Kickback Statute, Medicare and Medicaid regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals that take into account the “volume or value” of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). Such remuneration amounts to a kickback and can increase the expenditures paid by Government-funded health benefit programs by leading to overutilization of medical tests and inducing medically unnecessary and excessive reimbursements. Kickbacks also effectively reduce patients’ healthcare choices, because unscrupulous (or unknowing) physicians steer their patients to various products and procedures based on the physician’s own financial interests rather than the patients’ medical needs.

50. The Anti-Kickback Statute contains statutory exceptions and regulatory “safe harbors” excluding certain types of conduct from liability. *See* 42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952. None of these statutory exceptions or regulatory safe harbors applies to Defendants’ conduct in this matter.

51. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended that Act to impose administrative civil monetary penalties for Anti-Kickback Statute violations; \$50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or

received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

52. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that pharmaceutical drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as a result of Defendant's wrongdoing.

**C. Direct Federal Health Insurance Plans and Medical Pricing Contracts.**

**1. Direct Federal Health Insurance Plans.**

**a. TRICARE/CHAMPVA.**

53. TRICARE, administered by the Department of Defense ("DoD"), is the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

54. Similarly, CHAMPVA, administered by the Department of Veterans Affairs (the "VA"), provides healthcare coverage to qualified families of deceased or 100% disabled veterans.

**b. Federal Employees Health Benefits Plan (“FEHBP”).**

55. The FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. The FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management and collectively pay billions annually in medical benefits and reimbursements.

**2. The Anti-Kickback Act.**

56. Parties who contract or subcontract with the federal government are subject to the provisions of the Anti-Kickback Act. That law renders it impermissible for any person “to provide, attempt to provide, or offer to provide any kickback,” and defines ‘kickback’ to mean “any money, fee, commission, credit, gift, gratuity, *thing of value*, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor, or subcontractor employee *for the purpose of improperly obtaining or rewarding favorable treatment* in connection with a prime contract or in connection with a subcontract relating to a prime contract.” 41 U.S.C. §§ 52-53 (emphasis added). This broad language reflects Congress’s intent to prohibit even *attempts* to offer or provide a kickback, and to include a wide array of benefits and activities within its scope.

57. The Government has deemed such misconduct to be material to its decision to pay healthcare claims, in part through its requirement that providers certify compliance with this law as a condition of payment under, and participation in, Government healthcare programs. If the Government had been aware that pharmaceutical drugs were prescribed as a result of such prohibited conduct, the Government would not have paid the claims submitted as

a result of Defendant's wrongdoing.

**D. American Medical Association and American College of Physicians Ethics Policies.**

58. In recent years, responding to health care companies' providing "increasingly lavish" gifts and payments to doctors in connection with seminars, conferences, and sales representative visits, and entering into relationships both formal and informal that created financial incentives for physicians to prescribe or order particular companies' products, the American Medical Association ("AMA") adopted several Ethical Opinions. The AMA's purpose was to discourage physicians from accepting payments, gifts and incentives from industry, to avoid creating "relationship[s] that could influence the use of the company's products."

59. The AMA's opinion regarding "Gifts to Physicians from Industry" was adopted in 1990. (Opinion 8.061). That policy stated, in relevant part, that "[t]o avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

- (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. . . . Cash payments should not be accepted. . . .
- (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (*e.g.*, pens and notepads).
- (3) [A] legitimate "conference" or "meeting" [is defined] as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.
- (4) Subsidies to underwrite the costs of continuing medical

education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

- (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

\* \* \*

- (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

The AMA has further stated that these Guidelines "apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet." (Clarification of Opinion 8.061).

60. In 1998, with the stated purposes of "achiev[ing] the necessary goals of patient care" and "protect[ing] the role of physicians as advocates for individual patients," the AMA

adopted an Ethical Opinion regarding “Financial Incentives and the Practice of Medicine.”  
(Opinion 8.054).

61. Among other things, Opinion 8.054 advised:

- (1) [Physicians’] first duty must be to the individual patient. This obligation must override considerations of the reimbursement mechanism or specific financial incentives applied to a physician’s clinical practice.
- (2)(a) [Financial] incentives may create conflicts of interest that can in turn compromise clinical objectivity. . . . [I]t is important to recognize that sufficiently large incentives can create an untenable position for physicians.

62. The AMA’s Ethical Opinion regarding “Prescribing and Dispensing Drugs and Devices” requires doctors to “prescribe drugs, devices and other treatments based solely upon medical considerations and patient need and reasonable expectation of the effectiveness of the drug, device or other treatment for the particular patient.” The Opinion expressly prohibited physicians from accepting “any kind of payment or compensation from a drug company or device manufacturer for prescribing its products.” (Opinion 8.06).

63. Similarly, the American College of Physicians’ Ethics Manual (“Ethics Manual”) recognized “drug industry gifts” as having potentially negative influence on clinical judgment and noted that it was “unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells medical instruments or medications that are used in the care of the physician’s patients.” (Ethics Manual, “Financial Conflicts of Interest”). The Ethics Manual further advises:

The acceptance of individual gifts, hospitality, trips, and subsidies of all types from the health care industry by an individual physician is strongly discouraged. The acceptance of even small gifts has been documented to affect clinical judgment and heightens the perception (as well as the reality) of a conflict of interest. In addition to applying the Royal College of

Physicians' standard and asking "Would I be willing to have this arrangement generally known?", physicians should also ask "What would the public or my patients think of this arrangement?"; "What is the purpose of the industry offer?"; "What would my colleagues think about this arrangement?"; and "What would I think if my own physician accepted this offer?"

Physicians must critically evaluate all medical information, including that provided by detail persons, advertisements, or industry-sponsored educational programs. While providers of public and private graduate and continuing medical education may accept industry support for educational programs, they should develop and enforce strict policies maintaining complete control of program planning, content, and delivery. They should be aware of, and vigilant against, potential bias and conflicts of interest.

(Ethics Manual, "Financial Conflicts of Interest").

64. The Ethics Manual also advises that physicians receiving compensation as "speakers" or "consultants" could have "potential conflicts of interest" and warned that such arrangements "must not in any way compromise their objective clinical judgment or the best interests of patients . . ." (Ethics Manual, "Financial Conflicts of Interest").

## **VI. SPECIFIC ALLEGATIONS**

### **A. Defendants' Illegal Practices.**

#### **1. Off-Label Promotion.**

##### **a. Marketing Acute Pain Medicine Nucynta for Chronic Pain.**

65. Pricara's new acute-pain medication Nucynta (generic name tapentadol) is a centrally acting, DEA Class II narcotic. Tapentadol is a new molecular entity that acts both as an agonist at the mu-opioid receptor and as a norepinephrine reuptake inhibitor.

66. In or about June 2009, the FDA approved Nucynta for the treatment of moderate to severe acute pain. Acute pain differs from chronic pain in that acute pain is temporary (*e.g.*, resulting from a surgical operation or physical injury) whereas chronic pain

continues over an extended period of time (*e.g.*, lower-back pain resulting from osteoarthritis or slipped disk).

67. Despite the limited FDA approval for acute pain, Defendants have intensively marketed Nucynta for chronic pain. Tellingly, Pricara management instructed sales reps to market Nucynta to pain-management practitioners, who would rarely (if ever) have occasion to prescribe medications for acute pain, but instead generally prescribe medications for chronic pain.

68. For example, Defendants created and circulated detailing scripts directing Pricara sales reps to push Nucynta for back and neck pain patients, neither of which typically involves acute pain (particularly when such patients are being treated by pain management doctors). Reps were also instructed to cite clinical studies of the drug in patients with end-stage joint disease, which by definition does not involve acute pain (because the patient has no chance of recovery) but rather chronic pain.

69. Detailing and educational materials distributed to the sales force also touted clinical studies showing Nucynta's tolerability (*i.e.*, lack of side effects such as nausea and vomiting), including studies where patients took Nucynta for up to 90 days, which would not be an appropriate length of treatment for acute pain. Sales reps were told to reinforce this message with pain-management professionals because patients would be more compliant in taking their medication over the long term and thus get better pain management results. Again, this purported benefit of Nucynta would be of little importance to patients with acute pain, who would only take pain medication for a relatively short time.

70. Another way Defendants marketed Nucynta that demonstrates the off-label focus of Pricara's promotion is that they offered coupons for free 10-pill prescription refills.



Pricara management instructed the sales reps, including Mr. Obaitan, to get doctors to write three separate 10-day prescriptions (the standard prescription for acute pain is 10 pills, taken once a day. For each prescription, the patient would receive a coupon for a free 10-pill prescription. This would result in a total of a sixty-day supply of Nucynta as a *starting prescription*. Of course, acute pain (such as that associated with recovery from surgery or a broken bone) would not necessitate a sixty-day supply; however, a sixty-day supply is very typical for a starting prescription for the treatment of *chronic* pain. Again, the fact that Pricara was focusing this promotion on chronic pain providers illustrates its unlawful nature.

71. Indeed, despite its FDA approval, the chemical makeup of Nucynta makes it more appropriate and attractive for chronic pain than for acute pain, because it lacks the addictive properties of commonly-used opiates such as oxycontin. Nucynta is considered a “dual pathway” or “dual mechanism” pain medication, since it works on both the ascending and descending nerves, as do opiates. Pricara instructs its sales reps, including Mr. Obaitan, to tout these qualities in marketing Nucynta to chronic pain practitioners.

72. Even before Nucynta’s FDA approval in June 2009, Pricara sought to prepare the chronic pain market for the introduction of Nucynta through the “Neo-Pathways Campaign.” Sales reps were instructed to get doctors to participate in teleconferences and to fill out questionnaires, all of which were focused on chronic pain, not acute pain.

73. Pricara already sells a drug that is FDA approved and indicated for the treatment of chronic pain: Ultram (generic name tramadol HCl). However, in 2009 Ultram lost patent protection from generics and is now much less expensive, and much less profitable, than Nucynta. Pricara management instructed sales reps, including Mr. Obaitan, to use selling

Ultram as an excuse to get into pain management clinics, but then to push Nucynta as the better drug.

74. Pricara's unlawful marketing of Nucynta was known to, and actively promoted by, management. Among others, Jean Nycz, the Field Sales Director with responsibility for the Tampa, Florida area, and Holly Miller, the Tampa District Manager, who reported to Ms. Nycz through Regional Business Director Dale Shaw, oversaw the unlawful marketing programs in which Mr. Obaitan, a sales rep in the Tampa area, was instructed to participate.

75. In or about August 2009, shortly after the Nucynta program was launched, Ms. Nycz publicly praised Ms. Miller during a sales force meeting for her strong performance marketing the new product.

76. On one occasion in 2009, Ms. Miller accompanied Mr. Obaitan on a sales call to the CNS Group, a group of practicing neurologists which includes Dr. Ajay Aurora, Dr. Daniel Cabello, Dr. Michael Andriola, and Dr. Robert Vollbracht. Ms. Miller instructed Mr. Obaitan to talk to the doctors about the "dual mechanism" aspect of Nucynta, and that for that reason it would work on neuropathic (*i.e.* chronic) pain. Mr. Obaitan objected, explaining that while he could talk about the "dual mechanism" aspect, he insisted that he remind the doctors that Nucynta was not indicated for chronic pain, in the interest of full disclosure and fair balance. Ms. Miller chastised Mr. Obaitan, and indicated that the message she suggested was permissible, and that the doctors would "make the synaptic link" and understand that they were recommending Nucynta for chronic pain.

77. Likewise, on conference calls with the sales reps, Ms. Miller would ask whether neurologists and other customers were "picking up on" the chronic pain message she had instructed the reps to convey.

**b. Marketing Epilepsy/Migraine Medicine Topamax for Weight Loss**

78. Topamax (generic name topiramate), originally approved in 1996, currently has three FDA-approved indications: (1) initial monotherapy in epilepsy patients ten years old and up for treatment of partial onset or primary generalized tonic-clonic seizures; (2) adjunctive therapy for epilepsy patients age two and over with partial onset seizures or primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gestaut Syndrome; and (3) prevention of migraines in adults.

79. Defendants, through OMJP, have unlawfully marketed Topamax off-label to counteract the weight gain which is a side effect of many antipsychotic drugs. The improper nature of Defendants' marketing of Topamax for this off-label use was eminently clear to Mr. Obaitan, because management directed the sales force to target psychiatrists and other mental-health providers, who would not typically have occasion to prescribe medicines for epilepsy or migraines.

80. Weight gain associated with selective serotonin re-uptake inhibitor (SSRI) use is listed among the potential uses for Topamax in the DrugDex compendium (Sec. 4.5.Y). However, the compendium states that the evidence of Topamax's efficacy for that use is "inconclusive," that only one study suggested this use, and that "[l]arger, well-controlled studies are needed to further substantiate these results." Therefore, Defendants cannot properly rely on the compendium listing to support their improper off-label marketing of Topamax.

**2. Unlawful Use of Kickbacks to Induce Prescriptions**

81. Defendants routinely used monetary incentives to get doctors and other providers to prescribe their drugs, including in conjunction with the use of paid speakers to urge prescribers to write for off-label uses.

82. For example, Pricara selected its paid speakers using a proprietary Johnson & Johnson system (Vital Sign, which uses IMS prescriber data) that identifies the top decile of prescribers for a particular drug (including competing drugs). Speakers were paid approximately \$750-\$1,500. The unwritten rule at Pricara was that “if a doctor isn’t writing, he isn’t speaking.”

83. In the case of Nucynta, speakers were selected from chronic pain specialists. Paid speakers for Nucynta who participated in programs organized and attended by Mr. Obaitan included Dr. Sunil Panchel, Dr. Eric Haynes, Dr. Rodolpho Panganiban, and Dr. Andrew Gross, all of whom were pain-management specialists.

84. At the direction of management, including Holly Miller, Mr. Obaitan and other sales reps routinely brought Scientific Affairs Liaisons (“SALs”) along on their detailing visits to doctors’ offices. SALs are permitted to discuss off-label uses with doctors if such information is requested by the doctor; however, the common practice was to bring SALs on detailing visits unannounced and unrequested, where they would support Defendants’ off-label marketing. One such SAL was Doug Williamson, who marketed Topamax off-label for weight loss to psychiatrists, including Dr. Carl Jones.

**B. Damages Caused by Defendants’ Unlawful Marketing Schemes.**

85. As described herein, Defendants violated the federal and state False Claims Acts by engaging in fraudulent marketing, sales, and business practices which resulted in the federal and state governments paying for medical procedures they should not have paid for.

86. Upon information and belief, Defendants’ off-label and otherwise deceptive marketing of its drugs has resulted in damages to the government of tens of millions of dollars.

87. In marketing its drugs “off-label” and paying kickbacks to physicians, Defendants violated applicable statutes and regulations, including, but not limited to, the federal Food, Drug, and Cosmetic Act and Anti-Kickback Statute, as well as parallel provisions of state law.

88. By marketing “off-label” uses of its drugs, Defendants encouraged potentially unsafe uses which were not in accordance with FDA regulations. For example, Defendants’ off-label marketing of Risperdal for elderly patients with dementia significantly increased the patients’ risk of sudden death.

89. In providing kickbacks to physicians and other prescribers, Defendants undermined physicians’ and patients’ choice of appropriate treatment, creating the potential for patient harm. Patients who were prescribed Defendants’ drugs had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether their doctors were instead influenced by unlawful incentives provided by Defendants.

90. Because of illegal kickbacks, doctors more frequently prescribed Defendants’ drugs for Medicaid and Medicare patients and beneficiaries of other government healthcare programs than they may have otherwise, in violation of federal law.

91. Defendants’ illegal actions resulted in physicians, patients and pharmacies submitting reimbursement claims to Medicaid, Medicare and other government healthcare programs and obtaining millions of dollars worth of payments from the United States and the various States. Under the False Claims Acts, such claims were fraudulent because they sought reimbursement for drugs which were utilized as a result of illegal marketing and incentives. Had government-funded health insurance programs been aware that the drugs were prescribed

as a result of the conduct alleged in this Complaint, they would not have paid the claims submitted as a result of Defendant's wrongdoing.

## **VII. CLAIMS FOR RELIEF**

### **FIRST CAUSE OF ACTION**

(False Claims Act: Presentation of False Claims)  
(31 U.S.C. § 3729(a)(1)(A))

92. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

93. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

### **SECOND CAUSE OF ACTION**

(False Claims Act: Making or Using False  
Record or Statement to Cause Claim to be Paid)  
(31 U.S.C. § 3729(a)(1)(B))

94. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

95. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by defendant – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

**THIRD CAUSE OF ACTION**

(False Claims Act: Making or Using False Record  
Or Statement to Avoid an Obligation to Refund)  
(31 U.S.C. § 3729(a)(1)(G))

96. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

97. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants knowingly made, used or caused to be made or used false records or false statements—*i.e.*, the false certifications made or caused to be made by defendant—material to an obligation to pay or transmit money to the Government or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

**FOURTH CAUSE OF ACTION**

(False Claims Act: Conspiracy)  
(31 U.S.C. § 3729(a)(1)(C))

98. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if full set forth herein.

99. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants conspired to make or present false or fraudulent claims and performed one or more acts to effect payment of false or fraudulent claims.

**FIFTH CAUSE OF ACTION**

(Violations of Anti-Kickback Statute)  
(42 U.S.C. § 1320a-7a)

100. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

101. By engaging in the conduct described in the foregoing Paragraphs, the Defendants have violated 42 U.S.C. § 1320a-7a and 42 C.F.R. § 1001.952(f).

102. In particular, the Defendants have knowingly caused to be submitted claims to the United States Government and to Medicaid as a result of the payment of the above-described kickbacks. The payment of kickbacks to induce purchases constitutes remuneration to increase the level of business in violation of the Anti-Kickback Statute.

103. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for medical procedures which, had the Government known were utilized as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

#### **SIXTH CAUSE OF ACTION**

(California False Claims Act)  
(Cal. Govt. Code § 12651 *et seq.*)

104. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

105. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

106. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

107. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by



Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

108. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

109. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

#### **SEVENTH CAUSE OF ACTION**

(Delaware False Claims and Reporting Act)  
(Del Code Ann. tit. 6, § 1201 *et seq.*)

110. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

111. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

112. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

113. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

114. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

115. Pursuant to Del Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**EIGHTH CAUSE OF ACTION**

(Florida False Claims Act)  
(Fla. Stat. Ann. § 68.081 *et seq.*)

116. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

117. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

118. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

119. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

120. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

121. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**NINTH CAUSE OF ACTION**

(Georgia False Medicaid Claims Act)  
(Ga. Code. Ann. § 49-4-168.1 *et seq.*)

122. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

123. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

124. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

125. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

126. By reason of the Defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

127. Pursuant to Ga. Code. Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and

every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TENTH CAUSE OF ACTION**

(Hawaii False Claims Act)  
(Haw. Rev. Stat. § 661-21 *et seq.*)

128. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

129. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

130. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

131. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

132. By reason of the Defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

133. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**ELEVENTH CAUSE OF ACTION**

(Illinois Whistleblower Reward and Protection Act)  
(740 Ill. Comp. Stat. § 175/1 *et seq.*)

134. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

135. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

136. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

137. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

138. By reason of the Defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

139. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWELTH CAUSE OF ACTION**

(Indiana False Claims and Whistleblower Protection Act)  
(Ind. Code § 5-11-5.5-1 *et seq.*)

140. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

141. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

142. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

143. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

144. By reason of the Defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

145. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus at least \$5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**THIRTEENTH CAUSE OF ACTION**

(Louisiana Medical Assistance Programs Integrity Law)  
(La. Rev. Stat. Ann. § 46:439.1 *et seq.*)

146. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

147. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

148. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

149. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

150. By reason of the Defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

151. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**FOURTEENTH CAUSE OF ACTION**

(Massachusetts False Claims Law)  
(Mass. Gen. Laws ch. 12, § 5A *et seq.*)

152. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

153. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

154. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

155. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

156. By reason of the Defendant's acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

157. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.



**FIFTEENTH CAUSE OF ACTION**

(Michigan Medicaid False Claims Act)  
(Mich. Comp. Laws § 400.601 *et seq.*)

158. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

159. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

160. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

161. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

162. By reason of the Defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

163. Pursuant to Mich. Stat. § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud, three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**SIXTEENTH CAUSE OF ACTION**

(Nevada False Claims Act)  
(Nev. Rev. Stat. § 357.010 *et seq.*)

164. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

165. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

166. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

167. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

168. By reason of the Defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

169. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**SEVENTEENTH CAUSE OF ACTION**

(New Hampshire False Claims Act)  
(N.H. Rev. Stat. Ann. § 167:61-b)

170. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

171. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

172. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

173. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

174. By reason of the Defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

175. Pursuant to § 167:61-b, the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**EIGHTEENTH CAUSE OF ACTION**

(New Jersey False Claims Act)  
(N.J. Stat. Ann. § 2A:32C-1 *et seq.*)

176. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

177. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

178. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

179. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

180. By reason of the Defendant's acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

181. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty allowed under the federal False Claims Act, 31 U.S.C. § 3729, for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**NINETEENTH CAUSE OF ACTION**

(New Mexico Medicaid False Claims Act and Fraud Against Tax Payers Act)  
(N.M. Stat. Ann. § 27-14-1 *et seq.* and § 44-9-1 *et seq.*)

182. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

183. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

184. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

185. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

186. By reason of the Defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

187. Pursuant to N.M. Stat. Ann. § 27-14-4 and § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTIETH CAUSE OF ACTION**

(New York False Claims Act)  
(N.Y. State Fin. Law § 187 *et seq.*)

188. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

189. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

190. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

191. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

192. By reason of the Defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

193. Pursuant to N.Y. State Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of \$12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTY FIRST CAUSE OF ACTION**

(Oklahoma Medicaid False Claims Act)  
(63 Okla. St. Ann. § 5053 *et seq.*)

194. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

195. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

196. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

197. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

198. By reason of Defendant's acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

199. Pursuant to 63 Okl. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTY SECOND CAUSE OF ACTION**

(The State False Claims Act (Rhode Island))  
(R.I. Gen. Laws § 9-1.1-1 *et seq.*)

200. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

201. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

202. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

203. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

204. By reason of the Defendant's acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

205. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.



**TWENTY THIRD CAUSE OF ACTION**

(Tennessee Medicaid False Claims Act)  
(Tenn. Code Ann. § 71-5-181 *et seq.*)

206. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

207. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

208. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

209. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

210. By reason of Defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

211. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of \$25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTY FOURTH CAUSE OF ACTION**

(Texas Medicaid Fraud Prevention Law)  
(Tex. Hum. Res. Code Ann. § 36.002)

212. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

213. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

214. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

215. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

216. By reason of the Defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

217. Pursuant to Tex. Hum. Res. Code Ann. § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of \$15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTY FIFTH CAUSE OF ACTION**

(Virginia Fraud Against Taxpayers Act)  
(Va. Code Ann. § 8.01-216.1 *et seq.*)

218. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

219. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia Commonwealth Government for payment or approval.

220. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia Commonwealth Government to approve and pay such false and fraudulent claims.

221. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

222. By reason of Defendant's acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

223. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTY SIXTH CAUSE OF ACTION**

(Wisconsin False Claims for Medical Assistance Law)  
(Wisc. Stat. § 20.931)

224. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

225. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

226. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

227. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

228. By reason of the Defendant's acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

229. Pursuant to Wisc. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

**TWENTY SEVENTH CAUSE OF ACTION**

(District of Columbia False Claims Act)  
(D.C. Code Ann. § 2-308.03 *et seq.*)

230. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 91 of this Complaint as if fully set forth herein.

231. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

232. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

233. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

234. By reason of the Defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

235. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

### **VIII. DEMANDS FOR RELIEF**

**WHEREFORE**, Relator, on behalf of the United States Government, demands judgment against the Defendants, ordering that:

**As to the Federal Claims:**

a. Pursuant to 31 U.S.C. § 3729(a), Defendants pay an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729, *et seq*; \$50,000 for each violation of 42 U.S.C. § 1320a-7a(a)(7) of the Medicare/Medicaid Anti-Kickback Statute; and \$15,000 for each violation of 21 U.S.C. § 360 of the of the Food, Drug and Cosmetic Act, not to exceed \$1,000,000;

b. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law; and

d. Relator be awarded such other and further relief as the Court may deem to be just and proper.

**As to the State Claims:**

f. Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants within each State, all as provided by:

Cal. Govt. Code § 12651;  
6 Del. C. § 1201;

Fla. Stat. Ann. § 68.082;  
Ga. Code Ann. § 49-4-168.1;  
Haw. Rev. Stat. § 661-21;  
740 Ill. Comp. Stat. § 175/3;  
Ind. Code § 5-11-5.5-2 ;  
La. Rev. Stat. § 46:438.6;  
Mass. Gen. Laws Ch. 12 § 5B;  
Mich. Comp. Laws § 400.612;  
Nev. Rev. Stat. Ann. § 357.040;  
N.H. Rev. Stat. Ann. § 167-61-b;  
N.J. Stat. Ann. § 2A:32C-3;  
N.M. Stat. Ann. § 27-14-4 and § 44-9-3;  
N.Y. Fin. Law § 189.1(g);  
63 Okla. St. Ann. § 5053.1;  
R.I. Gen. Laws § 9-1.1-3;  
Tenn. Code Ann. § 71-5-182;  
Va. Code Ann. § 8.01-216.3;  
Wisc. Stat. § 20.931(2);  
D.C. Code Ann. § 2-308.14; and

g. Relator and Plaintiff State of Texas be awarded statutory damages in an amount equal to two times the amount of actual damages that Texas has sustained as a result of the defendant's actions within Texas, as well as the maximum statutory civil penalty for each violation of Tex. Hum. Res. Code Ann. § 36.052;

h. Relator be awarded his relator's share of any judgment to the maximum amount provided pursuant to:

Cal. Govt. Code § 12652(g)(2);  
6 Del. C. § 1205;  
Fla. Stat. Ann. § 68.085;  
Ga. Code Ann. § 49-4-168.2(i);  
Haw. Rev. Stat. § 661-27;  
740 Ill. Comp. Stat. § 175/4(d);  
Ind. Code § 5-11-5.5-6;  
La. Rev. Stat. § 46:439.4;  
Mass. Gen. Laws Ch. 12 § 5F;  
Mich. Comp. Laws § 400.610a;  
Nev. Rev. Stat. Ann. § 357.210;  
N.H. Rev. Stat. § 167:61-e;  
N.J. Stat. Ann. § 2A:32C-7;  
N.M. Stat. Ann. § 27-14-9 and § 44-9-7;

N.Y. State Fin. Law § 190.6;  
63 Okla. St. Ann. § 5053.4;  
R.I. Gen. Laws § 9-1.1-4;  
Tenn. Code Ann. § 71-5-183;  
Tex. Hum. Res. Code Ann. § 36.110;  
Va. Code Ann. § 8.01-216.7;  
Wisc. Stat. § 20.931(11); and  
D.C. Code Ann. § 2-308.15;

i. Relator be awarded all costs and expenses associated with each of the pendent State claims, plus attorney's fees as provided pursuant to:

Cal. Govt. Code § 12652(g)(8);  
6 Del. C. § 1205;  
Fla. Stat. Ann. § 68.086;  
Ga. Code. Ann. § 49-4-168.2(i);  
Haw. Rev. Stat. § 661-27;  
740 Ill. Comp. Stat. § 175/4(d);  
Ind. Code § 5-11-5.5-6;  
La. Rev. Stat. § 46:439.4;  
Mass. Gen. Laws Ch. 12 § 5F;  
Mich. Comp. Laws § 400.610a;  
Nev. Rev. Stat. Ann. § 357.180;  
N.H. Rev. Stat. § 167:61-e;  
N.J. Stat. Ann. § 2A:32C-8;  
N.M. Stat. Ann. § 27-14-9 and § 44-9-7;  
N.Y. State Fin. Law § 190.7;  
63 Okla. St. Ann. § 5053.4;  
R.I. Gen. Laws § 9-1.1-4;  
Tenn. Code Ann. § 71-5-183;  
Tex. Hum. Res. Code Ann. § 36.110;  
Va. Code Ann. § 8.01-216.7;  
Wisc. Stat. § 20.931(11); and  
D.C. Code Ann. § 2-308.15;

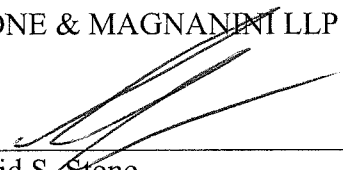
j. Relator and the State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

#### **TRIAL BY JURY**

Relator hereby demands a trial by jury as to all issues.



STONE & MAGNANINI LLP

By:   
David S. Stone  
Robert A. Magnanini  
Eric H. Jaso  
150 John F. Kennedy Parkway  
4<sup>th</sup> Floor  
Short Hills, New Jersey 07078  
973-218-1111  
*Attorneys for Relator*

Dated: December 20, 2010